UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,415	07/02/2001	James D. Talton	5853-186US	7896

7590 10/03/2002

Akerman Senterfitt & Eidon
Post Office Box 3188
West Palm Beach, FL 33402-3188

EXAMINER
WARE, TODD

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,415	TALTON ET AL.	
	Examiner	Art Unit	
	Todd D Ware	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of declaration filed 7-2-01, fax sent 7-27-01 and preliminary amendment filed 7-2-01 is acknowledged. The specification has been amended to include reference to the International Application and claims 1-27 have been canceled and new claims 28-70 have been added. Claims 28-70 are pending.

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species of the claimed invention: a) coated particles where the coating is continuous and b) coated particles where the coating is discontinuous.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

2. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 66-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 66-67 provide for the use of coated drug particles, but, since the claim does not set forth any steps involved in the method/process, it is unclear what

method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

8. The following is a quotation of the fourth paragraph of 35 U.S.C. 112:

> Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

9. Claims 46-47 fail to further limit the claim to which it refers. Claims 46-47 require that the coating layer is a discontinuous layer, however claim 28, the claim to which claims 46-47 refer, requires a coating. Such language does not set forth that portions of the particles are uncoated or discontinuous. As such, the dependent claims do not further limit as they do not include every limitation of the claim from which they depend.

Claim Rejections - 35 USC § 101

10. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claims 66-67 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. **Claims 28-42, 45, 48, 50-54, 59-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Moro et al (5,223,244; hereafter '244). Claim 48 is rejected in combination with Segal et al (4,678,772; hereafter '772). See MPEP 2131.01 for multiple 35 U.S.C. 102 rejections.**

14. '244 discloses aerosol compositions comprising a powder coated with a sheath powder. The average particle size of the core powder is 0.1 μm to 100 μm and the sheath powder is 1/5 the size of the core powder (C 2, L 12-44; C 3, L 25-27; examples; claims, especially 6-7). '244 also discloses that the active agent is glycyrrhizinate and that the weight percent is within the instant ranges. '772 is relied upon for disclosing that glycyrrhizin is an anti-inflammatory agent. '244 also discloses inclusion of a propellant in the aerosol formulations. No patentable weight is afforded the process limitations instant claims where the product is a product by process claim in the absence of evidence demonstrating a difference between the claimed product and that of the art (MPEP 3113). The patentability of the product claimed and not of the recited steps that must be established.

$\frac{1}{5} \times 0,1 = 0,02\,\mu m = 2nm$

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. **Claims 28-45, 48, 50-54, 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moro et al (5,223,244; hereafter '244). Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moro et al (5,223,244; hereafter '244) rejected in view of Segal et al (4,678,772; hereafter '772).**

19. '244 teaches aerosol compositions comprising a powder coated with a sheath powder. The average particle size of the core powder is 0.1 μm to 100 μm and the sheath powder is 1/5 the size of the core powder (C 2, L 12-44; C 3, L 25-27; examples; claims, especially 6-7). '244 also discloses that the active agent is glycyrrhizinate and that the weight percent is within the instant ranges. '772 is relied upon for teaching that glycyrrhizin is an anti-inflammatory agent. '244 also discloses inclusion of a propellant in the aerosol formulations. Particles smaller than those taught in '244 do not appear to be critical since the instant specification teaches that the invention may be achieved with particle sizes taught in '244. No patentable weight is afforded the process limitations instant claims where the product is a product by process claim in the absence of evidence demonstrating a difference between the claimed product and that of the art (MPEP 3113). The patentability of the product claimed and not of the recited steps that must be established. '244 does not set forth specific examples utilizing sheath particles made of cellulose compounds. However, the small genus set forth and specific recitation of the indicated biodegradable sheath particles establishes that it would have been obvious to one skilled in the art at the time of the invention to construct the sheath particles accordingly, with the expectation of similar results and where the motivation is based upon the availability of the ingredients for the sheath particles.

20. **Claims 28-45, 48-61, and 66-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakon et al (5,972,388; hereafter '388).**

21. '388 teaches an ultrafine particle powder for inhalation where the particle powder is produced by spray-drying a mixture of active agent and a lower alkyl ether cellulose where the active and cellulose are either dissolved or suspended in a solution and then spray-dried into particles that are as small as 500 nm. Particles smaller than this size do not appear to be critical since size criticality appears to depend upon administration to lower airways which is achieved with '388. Such is also the case for thickness of the coating layer. '388 also teaches that the active is triamcinolone acetonide or a bronchodilator and that mixtures of actives are contemplated.

22. **Claims 28-45, and 48, 59-61, and 66-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanes et al (5,855,913; hereafter '913). Claims 49 and 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanes et al (5,855,913; hereafter '913) in combination with Cutie (6,129,905; hereafter '905) and further in combination with Goodman and Gilman (1996).**

23. '913 teaches aerodynamically light particles for inhalation where the particles are produced by emulsifying active agent in polymer such as PLA or PLGA in a volatile solvent. After mixing, the mixture is spray-dried and the volatile solvent is evaporated to leave drug particle enclosed within polymer. The particles of '913 are as small as 2 μm. Particles smaller than this size do not appear to be critical since size criticality appears to depend upon administration to lower airways which is achieved with ~~'388~~ '913. Such is also the case for thickness of the coating layer.

24. '913 teaches inclusion of active agents such as the bronchodilators, steroids and antibiotics. '913 does not teach mixtures of drugs nor the drugs of instant claim 49.

25. '905 is relied upon for teaching mixtures of drugs such as the bronchodilators of '905 and steroids such as triamcinolone acetonide.

26. Goodman and Gilman is relied upon for teaching that these agents are effective for treating asthma and respiratory-related allergies.

27. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine '913 and '905 and provide mixtures of bronchodilators and triamcinolone acetonide with the motivation of providing a combined/additive effect for treating asthma and respiratory-related allergies.

28. **Claims 62-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanes et al (5,855,913; hereafter '913) in view of Bucks et al (6,277,364; hereafter '364) or Sakon et al (5,972,388; hereafter '388) in view of Bucks et al (6,277,364; hereafter '364) or over Moro et al (5,223,244; hereafter '244) in view of Bucks et al (6,277,364; hereafter '364).**

29. '913, '388 and '244 are all relied upon for all that they teach as stated previously. None of these references teach a kit having instruction.

30. '364 is relied upon for teaching aerosol kit formulations and instructions for their use.

31. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to formulate a composition of '913, '388 or '244 with the motivation of

providing instructions for use, suggested storage conditions, and shelf-life expectancy for the products.

Double Patenting

32. Applicant is advised that should claim 28 be found allowable, claim 50 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

33. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

34. Claims 68-70 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,406,745. Although the conflicting claims are not identical, they are not patentably distinct from each other because the size of the particles in '745 is the genus of the size of the instant particles.

Conclusion

35. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw
September 30, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600